



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 3, 2015

Natec Medical Ltd.
c/o Ms. Judith Danielson
Senior Regulatory Consultant
CardioMed Device Consultants, LLC
5523 Research Park Drive
Suite 205
Baltimore, MD 21228

Re: K142459

Trade/Device Name: Ebony PTA 0.014" Rx Peripheral Dilatation Catheter

Regulation Number: 21 CFR 870.1250

Regulation Name: Percutaneous Catheter

Regulatory Class: Class II

Product Code: LIT

Dated: December 2, 2014

Received: December 3, 2014

Dear Ms. Danielson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number (if known)

Device Name

Ebony® PTA 0.014" RX Peripheral Dilatation Catheter

Indications for Use (Describe)

The Ebony® PTA 0.014" RX Peripheral Dilatation Catheter is intended for dilatation of lesions in the iliac, femoral, popliteal, infra popliteal, and renal arteries. This catheter is not intended for use in coronary or neuro-vasculature.

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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Ebony® PTA 0.014" RX Peripheral Dilatation Catheter
510(k) SUMMARY
21 CFR 807.92

Applicant:

Company Name: Natec Medical Ltd.
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Reduit, Mauritius
Telephone: +230 466 30 54
Fax: +230 466 67 70

Contact Person: Xavier De Buchere
Regulatory Affairs & Quality Manager
xdbuchere@natec-medical.com

Summary Preparation Date: August 17, 2014

Device Name:

Trade Name: Ebony® PTA 0.014" RX Peripheral Dilatation Catheter
Common/Usual Name: PTA Catheter
Classification Name: Percutaneous Transluminal Angioplasty Catheter
Regulation Number: 21 CFR 870.1250
Product Code: LIT
Device Class: Class II

Predicate Devices:

- Ebony® PTA 0.014" RX Peripheral Dilatation Catheter (K112513)
- ev3 Inc., RapidCross™ PTA Rapid Exchange Balloon Dilatation Catheter (K123544)
- ev3 Inc., NanoCross™ Elite 0.014" Over-the-Wire PTA Balloon Dilatation Catheter (K141118)

Device Description:

The EBONY® PTA 0.014" RX Dilatation Catheter is a standard rapid exchange (RX) PTA catheter with a semi-compliant inflatable balloon and tapered tip on the distal end. Two radiopaque markers facilitate proper balloon positioning across the stenosis, and a hydrophilic coating facilitates advancement of the catheter through the vasculature.

The modified EBONY® PTA 0.014" RX Dilatation Catheter line extension adds a 1.5 mm diameter balloon and additional balloon lengths to the currently available sizes.

Indication for Use:

The Ebony® PTA 0.014" RX Catheter is intended for dilatation of lesions in the iliac, femoral, popliteal, infra popliteal, and renal arteries. This catheter is not for use in coronary or neuro-vasculature.

Technological Characteristics:

The modified Ebony® PTA 0.014" RX Peripheral Dilatation Catheter has the same indication for use and is manufactured using the same rapid exchange design and materials as the Ebony® PTA 0.014" RX Peripheral Dilatation Catheter cleared under K112513.

The balloon size matrix of the Ebony® PTA 0.014" RX Peripheral Dilatation Catheter was modified to include 1.5 mm diameter balloons, and longer balloon lengths (up to 200 mm) to the previously cleared balloon sizes. The new balloon sizes are similar to ev3's NanoCross™ Elite 0.014" PTA catheter with 1.5 mm diameter balloon, and RapidCross™ PTA Catheter with balloon lengths ranging up to 210mm long.

Performance Data:

Based on a risk analysis, the following bench testing was performed on the modified Ebony® PTA .014" RX Catheter:

- Balloon compliance
- Balloon burst pressure
- Balloon fatigue
- Shaft resistance (Torque Test)
- Bond strength
- Catheter dimensions
- Deflation time
- Guide wire and introducer compatibility.

Conclusion

The modified Ebony® 0.014" RX Peripheral Dilatation Catheters and the predicate Ebony® 0.014" RX Peripheral Dilatation Catheter (K112513) have the same intended use, same materials and the same RX design. The new balloon sizes met all of the verification/validation acceptance criteria and demonstrated that the modified Ebony® 0.014" RX Peripheral Dilatation Catheters are as safe and effective as the predicate device.